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10/716,649	11/19/2003	John F. Chiarello	AM 101194	7650
25291	7590	07/12/2005	EXAMINER	
WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			STOCKTON, LAURA	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,649

Applicant(s)

CHIARELLO ET AL.

Examiner

Laura L. Stockton, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 15, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,24-29 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,24-29 and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Claims 1, 3-10, 24-29 and 31-35 are pending in the application.

Election/Restrictions

Applicants' election without traverse of Group I, and the species of Example 29 in Table I on page 17 of the instant specification, in the reply filed on November 22, 2004 is acknowledged. The entire scope of elected Group I has been examined.

Rejections made in the previous Office Action that do not appear below have been overcome. Therefore, arguments pertaining to these rejections will not be addressed.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-10, 29 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No support in the instant specification or the originally filed claims can be found for the proviso which states "then (R)_n cannot be 2,6-dihalo-4-trifluoromethyl". Applicants did not state where such language could be found in the instant specification

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(page number and line number). Applicants should specifically point out the support for any amendments. See M.P.E.P. §§ 714.02 and 2163.06. Therefore, the claims lack written description as such.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 24-28 and 31-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 10, 24, 26 and 35, an "and" should be added before the last compound listed.

In claim 31, it is not possible to have a C₁-C₁₀ alkyl ketone.

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Response to Arguments

In the response filed April 15, 2005, Applicants state that all inadvertent errors had been addressed by the amendment to the claims. In response, the "and" was not added to the claims before the last compound listed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by:

a) Hatton et al. {U.S. Pat. 5,232,940} - see compound 154 in column 12, lines 67-68 (and also column 19, lines 19-29; column 20, lines 13-15; and column 21, lines 7-16); or

b) Hatton et al. {WO 87/03781} - see compound 46 on page 15, lines 13-15 (and also page 31, line 25; and page 32, lines 21-23).

Each of the above cited prior art disclose products embraced by the instant claimed invention. Therefore, the instant claimed invention is anticipated by each of the above cited references.

Response to Arguments

In the response filed April 15, 2005, Applicants argue that neither of the above cited references

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disclosure a particular pour-on composition and recited ingredients.

In response, each of the Hatton et al. references disclose 5-amino-3-cyclopropyl-1-[2,6-dichloro-4-trifluoromethyl)phenyl]-1H-4-carbonitrile which can be used in a veterinary pour-on composition that comprises, for example, an aromatic hydrocarbon {i.e., xylene}. See column 19, lines 19-25 and column 21, lines 7-16 in '940; and page 31, line 25 and page 36, lines 13-24 in '781. Therefore, each of the Hatton et al. references does anticipate the instant claimed invention.

Claims 1, 3-10, 26-29 and 31-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Furch et al. {WO 03/029222}.

Furch et al. disclose, for example, Compound No. I.1-3 on page 51 (also see page 41, lines 16-30; page

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44, line 19; page 47, lines 22-28, 46 and 47; and page 48, lines 1-4) that is embraced by the instant claimed invention, and therefore, the instant claimed invention is anticipated.

Response to Arguments

In the response filed April 15, 2005, Applicants argue that the claims, as amended, do not overlap with the compounds of Furch et al. Applicants further argue that Furch et al. do not describe the specific veterinary pour-on compositions.

In response, Applicants' arguments are not persuasive because, although the instant claims have been amended, the instant claimed invention is still anticipated by Furch et al. See, for example, Compound No. I.1-3 {CA Registry No. 508228-97-5} on page 51 in Furch et al. which is the same as the now first compound listed in, for example, instant claim 10. Further, Furch et al. disclose veterinary pour-on

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compositions comprising, for example, xylene (page 41, lines 4-30 and page 47, lines 21-27).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-10, 24-29 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatton et al. {U.S. Pat. 5,232,940}, Hatton et al. {WO 87/03781} and Furch et al. {WO 03/029222}, each taken alone or in combination with each other.

Determination of the scope and content of the prior art (MPEP

§2141.01)

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Applicants claim N-phenylpyrazole compounds. Each of **Hatton et al. '940** (the abstract ; column 2, lines 4-20; column 3, lines 1-26; columns 15-17; column 19, lines 19-29; column 20, lines 13-15; column 21 and especially compound 154 in column 12, lines 67-68), **Hatton et al. '781** (the abstract; pages 3-6, 24-28, 31-40; and especially compound 46 on page 15, lines 13-15) and **Furch et al.** (pages 1, 2, 37-42 and 46; and especially Compound No. I.1-3 on page 51) teach N-phenylpyrazole compounds that are either structurally the same as (see above 102 rejections) or structurally similar to the instant claimed compounds.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The difference between some of the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

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*Finding of prima facie obviousness--rational and motivation (MPEP
§2142-2413)*

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., a pesticide).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful as a pesticide. Since each of the prior art teach pesticidal N-phenylpyrazole compounds, the combination of the prior art references would also teach Applicants' invention. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

Response to Arguments

In the response filed April 15, 2005, Applicants state that to establish a *prima facie* case of obviousness, the guideline of M.P.E.P. §706.02(j) and case law provide three basic criteria which are: (1) there must be some suggestion or motivation to modify; (2) there must be a reasonable expectation of success; and (3) the combined references must teach or suggest all claim limitations. Applicants argue that the prior art itself fails to provide the suggestion or motivation of the desirability of combining or modifying the references, either taken alone or in combination with each other.

Applicants' arguments have been considered but have not been found persuasive. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.

As stated above, each of the prior art references disclose products embraced by the instant claimed invention. See the above noted pages or columns for the genera in each of the prior art references and especially Compound 154 in column 12, lines 67-68 in Hatton et al.'940; Compound 46 on page 15, lines 13-15 in Hatton et al. '781 and Compound No. I.1-3 on page 51.

2. Ascertaining the differences between the prior art and the claims at issue.

The difference between some of the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

3. Resolving the level of ordinary skill in the pertinent art.

The motivation to make the claimed compounds derives from the expectation that structurally similar

compounds would possess similar activity (e.g., a pesticide).

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful as a pesticide. Since each of the prior art teach pesticidal N-phenylpyrazole compounds, the combination of the prior art references would also teach Applicants' invention.

Applicants' argue that the efficacy data found on pages 18-24 of the instant specification proves that a little structural change can significantly impact the biological properties and potencies of the compounds. Applicants argue that similar properties or uses to

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those seen in the art would not be expected from the instantly claimed compounds and therefore, since the art is not predictable, the cited references do not render the claimed invention obvious. Applicants' argue that there is an art-recognized problem that many ectoparasitocidal compounds have lost considerable efficacy over time due to development of resistant strains of parasites. Applicants further argue that none of the references describe all the claim limitations or suggest the desirability of putting these particular ingredients together in a unique pour-on formulation.

All of Applicants' arguments have been considered but have not been found persuasive. The data in the instant specification has been considered. In comparing, for example, the "EVALUATION OF THE EFFICACY OF TEST COMPOUNDS AGAINST ADULT TICKS" found on page 20 of the instant specification, it would appear that Example 19 of the present invention (also corresponds

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to the specific compounds highlighted above in each of the Hatton et al. references) has a better mortality rate at a 7.80 concentration (ug/cm²) than instant Example 29, the elected species. Additionally instant Example 4 (which corresponds to Compound No. I.1-34 on page 53 of Furch et al.) should better consistent activity over instant Example 19 (also found in each Hatton et al.) and instant Example 29 (the elected species) in both efficacy showings on pages 19 and 20. Therefore, it would appear that the prior art, especially the compounds found in Furch et al., show better, consistent or the same activity over the instant claimed invention. Further, as stated above, each of the prior art references disclose the instant claimed pour-on formulations. For all the reasons given above, the instant claimed invention would have been suggested to one skilled in the art and therefore, would have been obvious to one skilled in the art.

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The elected species of Example 29 (Table I on page 17 of the instant specification) is not allowable over the art of record. See Compound No. I.1-40 on page 53 of Furch et al. {WO 03/029222}.

Conclusion

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed,

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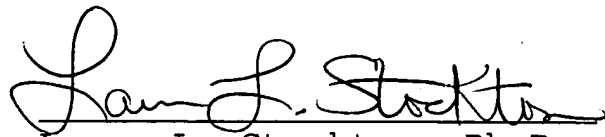
and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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The Official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

A handwritten signature in cursive script, reading "Laura L. Stockton". The signature is written in black ink and is positioned above the printed name.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

July 11, 2005